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			3761	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mail@ipcounselors.com

	Application No.	Applicant(s)	
	10/811,055	CLINE, JOHN B.	
Office Action Summary	Examiner	Art Unit	
	Ginger T. Chapman	3761	
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet wi	h the correspondence address	
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC 1.136(a). In no event, however, may a re- od will apply and will expire SIX (6) MON ute, cause the application to become AB	CATION.  Sply be timely filed  IHS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133).	
Status			
Responsive to communication(s) filed on 10 2a) This action is <b>FINAL</b> . 2b) ▼ The 3 Since this application is in condition for allow closed in accordance with the practice under	nis action is non-final. vance except for formal matte	·	
Disposition of Claims			
4) ☐ Claim(s) 35-38 and 40-60 is/are pending in t 4a) Of the above claim(s) is/are withdi 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 35-38,40-48 and 50-60 is/are reject 7) ☐ Claim(s) 49 is/are objected to. 8) ☐ Claim(s) are subject to restriction and	rawn from consideration.		
Application Papers			
9) ☐ The specification is objected to by the Examination The drawing(s) filed on 26 March 2004 is/are Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the	: a)⊠ accepted or b)□ objusted drawing(s) be held in abeyant ection is required if the drawing(	ce. See 37 CFR 1.85(a). s) is objected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a lie	nts have been received. nts have been received in A iority documents have been eau (PCT Rule 17.2(a)).	oplication No received in this National Stage	
Attachment(s)  1)		ummary (PTO-413)	
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date		)/Mail Date formal Patent Application ·	

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## **DETAILED ACTION**

## **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 September 2010 has been entered.

#### Status of the Claims

Claims 35-38 and 40-60 are pending in the application.

### Claim Objections

Claim 48 is objected to because of the following informalities: line 2 recites "an gas", this appears to be a typographical error of "a gas". Appropriate correction is required.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 35-38, 40-48 and 50-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al (US 6,689,111 B2) in view of Kay (US 4,596,566).

With respect to claim 35, Mulhauser discloses an ostomy device for sealing a stoma to control the passage of liquid and solid waste material through the stoma 14 (column 1, lines 7-8; column 2, lines 55-56), said device comprising recess defining means B; adhesive means 26, C comprising a continuous, uninterrupted adhesive layer situated between and in direct contact with said recess defining means B and the skin 18 surrounding the stoma 14 (column 4, lines 57-61; column 5, lines 36-40; column 6, lines 50-53; Figures 1 and 3), completely surrounding and enclosing the stoma on all sides A, 16, F, E (Figure 3; column 6, lines 50-51) for securing said recess defining means B to the body such that said recess defining means B forms a seal A, 16 (Figure 3) with the body completely surrounding and enclosing the stoma on all sides A, 16, F, E (Figures 1 and 2; column 5, lines 36-40 and lines 27-30; column 6, lines 31-32 and 39-44); and stoma covering means 16, situated externally to the body 18, over the stoma 14 (column 4, lines 56-58; column 5, lines 37-40; Figures 1-3), within said recess defining means B, and comprising a continuous, uninterrupted member A, 16 adapted to prevent passage of liquid and solid waste through the stoma when pressed against the stoma (column 6, lines 39-47), said recess defining means B defining 10, with said stoma 14 covering means A, 16 a chamber (column 4, lines 54-61, Figure 1), said chamber comprising a fluid entrance port 20 (Figure 1; column 4, line 62) and being situated over said stoma covering means B, said chamber being pressurizable with fluid through said fluid entrance port 20 to press said stoma covering means A, 16 against the stoma 14 (column 6, lines 22-24; column 5, lines 25-35; column 6, lines 31-33) and further comprising

means for sealing 21 said fluid entrance port 20 (column 4, lines 62-65) to prevent the fluid from escaping said chamber after it is pressurized (column 5, lines 6-9).

Mulhauser discloses the claimed invention except for the device being situated entirely externally to the body. Mulhauser discloses, at column 6, lines 13-15, that because a portion A of the sealing member A, 16 is a flexible thin film, a portion A of sealing member could be inserted into the stoma 14. Thus Mulhauser discloses that portion A is capable of being situated internally to the body when suctioned inward against the stoma and bowel wall and thus portion A is also capable of covering the stoma without being situated partially internally if the tension on the film is increased so that it does not get suctioned into the stoma, and would appear to work equally well, as evidenced by the prior art film and the instant film form the substantially identical type of sealing (column 6, lines 39-49). Mulhauser provides motivation for a seal occluding the stoma (column 2, lines 6-10 and lines 54-56); there are only two possible locations for the seal to be positioned with respect to the stoma in order to seal the stoma, either over the stoma or within the stoma, in order to seal the stoma, and even the embodiments wherein the seal has a portion internally of the body, the seating portion must be situated externally of the body to retain the seal against the stoma, therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to try positioned the seal in either of these two locations with a reasonable amount of success.

Mulhauser discloses that sealing member A is in the form of a thin flexible membrane in the shape of a balloon that can intrude into the stoma against the internal bowel wall (column 2, lines 7-9). Mulhauser further discloses at column 2, lines 25-31 and column 5, lines 10-30, that the thin flexible film sealing member A can have a variety of configurations to maximize seal

effectiveness; thus Mulhauser contemplates that the flexible film can have a variety of other configurations.

Mulhauser discloses that the preferred shape for the flexible film is a tube-like configuration with a bulbous end to contact the bowel wall in the region proximal to the abdominal wall surrounding the stoma, i.e. a balloon type of configuration. Mulhauser discloses that because of the flexible and compliant nature of member A, it reacts to temporary increases in internal bowel pressure by contracting slightly and its flexible nature gives it freedom to move and conform to local changes in bowel pressure and shape. Thus one of ordinary skill would expect the film to suction inwardly as it contracts slightly and bellow within the stomal opening in response to increases and decreases in internal bowel pressure.

Mulhauser discloses at column 5, lines 10-14, that the member A is formed of the substantially identical materials disclosed in the instant specification at paragraph [0061] as suitable embodiments of the instant thin flexible film, and the film of Mulhauser, prior to being inserted within the stoma, will in its starting position, be in the form of a film covering the external surfaces of the stoma. Mulhauser discloses at column 6, lines 22-45, that when the thin flexible film is pressurized it protrudes into the bowel, i.e. it is sucked toward the user, and creates an imperfect seal that permits flatus gas to flow in the wrinkles formed in the film and stomal skin but the film blocks semi-solid stool passage in the substantially identical manner that the instant film operates to permit flatus flow and block semi-solid stool.

Therefore the only difference between the seal of Mulhauser and the instant seal is that the seal of Mulhauser protrudes slightly into the stoma while the instant seal lays flat over the stoma, however, since the instant seal will also be flexible and compliant, and will also form an

imperfect seal with slight wrinkles forming leak paths identical to that of Mulhauser, one of ordinary skill in the art would expect it to respond in the same manner to temporary increases in internal bowel pressure by also contracting slightly, and thus in even in the configuration wherein the film overlies and covers the stoma the instant film will also tend to be sucked slightly into the stoma as it contracts in response to changes in internal bowel pressure in the same manner as the prior art film.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that the thin flexible seal film of Mulhauser could either be in a form where it protrudes into the stoma or lies flat over the stoma as these are the only possible two locations for the film and in either instance the film will contract into the stoma in response to temporary increases or decreases in internal bowel pressure.

In the alternative, Kay discloses an ostomy device comprising a chamber being pressurizable with fluid, thus providing motivation for such. As best depicted in Figures 13-15, Kay discloses wherein the seal 22 is a thin flexible film that is situated entirely externally to the body and comprising recess defining means 80, 82 (column 7, lines 5-26). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the seal of Mulhauser externally to the body as taught by Kay since Kay states, at column 26-29, that the benefit of providing the seal with this design is that it also is sucked toward the user in response to being pressurized and creates an optimum faceplate to body seal to the users body.

With respect to claim 36, as best depicted in Figure 3, Mulhauser discloses wherein said stoma covering B means comprises a flexible membrane A, F (column 5, lines 10-14; column 3, lines 61-63).

With respect to claim 37, as best depicted in Figures 2 and 3, Mulhauser discloses wherein said stoma covering B means has an edge 16 and wherein said edge 16 is fixed to the interior of said recess defining means A (column 4, lines 54-56; column 5, lines 52-53; column 6, lines 6-10).

With respect to claim 38, Mulhauser discloses means D for pressurizing said chamber (column 6, lines 22-26).

With respect to claim 40, as best depicted in Figures 1 and 6, Mulhauser discloses wherein said fluid entrance port 20 comprises an inlet port 21 and said sealing means A comprises a one-way valve 21 associated with said port (column 4, lines 62-65).

With respect to claim 41, Mulhauser discloses wherein said pressurizing means D comprises pump means integral with said recess defining means B (column 6, lines 28-29).

With respect to claim 42, as best depicted in Figures 2 and 6, Mulhauser discloses wherein said pressurizing means D comprises flexible 22, 23 means affixed to said recess defining means B, said flexible 22, 23 means having a variable volume which can be reduced by the application of pressure (column 4, lines 66-67) on said flexible means 22, 23 and said entrance port 20 connects said flexible means 22, 23 and said chamber (column 6, lines 22-28; column 2, lines 15-20).

With respect to claim 43, Mulhauser discloses wherein said sealing means comprises a one-way valve 21 associated with said entrance port 20 (column 4, lines 62-65).

With respect to claim 44, Mulhauser discloses means 25 for limiting pressure in said chamber (column 6, lines 30-38).

With respect to claim 45, Mulhauser discloses wherein said pressure limiting means 25 comprises a pressure relief valve (column 6, lines 30-38).

With respect to claim 46, Mulhauser discloses the device of claim 35 in combination with an external pressurization device 23 (column 6, lines 22-24).

With respect to claim 47, Mulhauser discloses venting means 30 in said recess defining means B (column 6, lines 45-49).

With respect to claim 48, as best depicted in Figures 4-6, Mulhauser discloses wherein said venting means 30 comprises an outlet port and a gas filtration 30 means associated with said outlet port (column 6, lines 45-49).

With respect to claim 50, Mulhauser discloses wherein said securing means E comprises means C for engaging said recess defining means B and means for adhering 26 said engaging means C to the tissue 18 surrounding the stoma 14 (column 4, lines 56-61; column 5, lines 37-40 and lines 48-55).

With respect to claim 51, Mulhauser discloses wherein said engaging means E comprises means for removably engaging said recess defining means B (column 5, lines 48-49).

**With respect to claim 52**, Mulhauser discloses the device of claim 34 for use with waste collection means F (column 5, lines 48-50).

With respect to claim 53, Mulhauser discloses wherein said waste collection means F comprises a collection pouch (column 5, lines 48-50 and column 7, lines 1-2).

With respect to claim 54, as best depicted in Figure 2, Mulhauser discloses wherein said waste collection means F has an end connected to said securing means E.

With respect to claim 55, as best depicted in figures 2 and 5, Mulhauser discloses wherein said waste collection F means is collapsible (column 7, lines 7-8).

With respect to claim 56, Mulhauser discloses wherein said waste collection pouch F has a concertina-like configuration (column 7, lines 14-16).

With respect to claim 57, as best depicted in Figure 2, Mulhauser discloses wherein said waste collection means comprises a collection pouch F, said pouch F comprising a flexible wall having first and second ends fixed between said recess defining means B and said securing means E 32, respectively.

With respect to claim 58, as best depicted in Figure 2, Mulhauser discloses wherein said collection pouch F is elongated.

With respect to claim 59, Mulhauser an ostomy device for sealing a stoma to control the passage of liquid and solid waste material through the stoma 14 (column 1, lines 7-8; column 2, lines 55-56), said device being situated externally 18 to the body and comprising recess defining means B; adhesive means C situated between and in direct contact with said recess defining means B and the skin 18 surrounding the stoma 14 comprising a continuous, uninterrupted adhesive layer 26 completely surrounding and enclosing the stoma 14 on all sides A, 16, F, E for

securing said recess defining means B to the body such that said recess defining means B forms a seal A with the body completely surrounding and enclosing the stoma on all sides A, 16, F, E (Figure 3; column 6, lines 50-51); and stoma covering means 16, situated within said recess defining means B, and comprising a member A adapted to prevent passage of liquid and solid waste material through the stoma when pressed against the stoma (column 6, lines 39-47), said recess defining B means defining, with said member A, a chamber with a sealable fluid entrance port 20, said chamber being situated over said stoma covering means 16 and pressurizable through said fluid entrance port 20 to press said member against the stoma (column 6, lines 31-33).

Mulhauser discloses the claimed invention except for the device being situated entirely externally to the body. Mulhauser discloses, at column 6, lines 13-15, that because a portion A of the sealing member A, 16 is a flexible thin film, a portion A of sealing member could be inserted into the stoma 14. Thus Mulhauser discloses that portion A is capable of being situated internally to the body when suctioned inward against the stoma and bowel wall and thus portion A is also capable of covering the stoma without being situated partially internally if the tension on the film is increased so that it does not get suctioned into the stoma, and would appear to work equally well, as evidenced by the prior art film and the instant film form the substantially identical type of sealing (column 6, lines 39-49). Mulhauser provides motivation for a seal occluding the stoma (column 2, lines 6-10 and lines 54-56); there are only two possible locations for the seal to be positioned with respect to the stoma in order to seal the stoma, either over the stoma or within the stoma, in order to seal the stoma, and even the embodiments wherein the seal has a portion internally of the body, the seating portion must be situated externally of the body to

retain the seal against the stoma, therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to try positioned the seal in either of these two locations with a reasonable amount of success.

Mulhauser discloses that sealing member A is in the form of a thin flexible membrane in the shape of a balloon that can intrude into the stoma against the internal bowel wall (column 2, lines 7-9). Mulhauser further discloses at column 2, lines 25-31 and column 5, lines 10-30, that the thin flexible film sealing member A can have a variety of configurations to maximize seal effectiveness; thus Mulhauser contemplates that the flexible film can have a variety of other configurations.

Mulhauser discloses that the preferred shape for the flexible film is a tube-like configuration with a bulbous end to contact the bowel wall in the region proximal to the abdominal wall surrounding the stoma, i.e. a balloon type of configuration. Mulhauser discloses that because of the flexible and compliant nature of member A, it reacts to temporary increases in internal bowel pressure by contracting slightly and its flexible nature gives it freedom to move and conform to local changes in bowel pressure and shape. Thus one of ordinary skill would expect the film to suction inwardly as it contracts slightly and bellow within the stomal opening in response to increases and decreases in internal bowel pressure.

Mulhauser discloses at column 5, lines 10-14, that the member A is formed of the substantially identical materials disclosed in the instant specification at paragraph [0061] as suitable embodiments of the instant thin flexible film, and the film of Mulhauser, prior to being inserted within the stoma, will in its starting position, be in the form of a film covering the external surfaces of the stoma. Mulhauser discloses at column 6, lines 22-45, that when the thin

flexible film is pressurized it protrudes into the bowel, i.e. it is sucked toward the user, and

creates an imperfect seal that permits flatus gas to flow in the wrinkles formed in the film and

stomal skin but the film blocks semi-solid stool passage in the substantially identical manner that

the instant film operates to permit flatus flow and block semi-solid stool.

Therefore the only difference between the seal of Mulhauser and the instant seal is that the seal of Mulhauser protrudes slightly into the stoma while the instant seal lays flat over the stoma, however, since the instant seal will also be flexible and compliant, and will also form an imperfect seal with slight wrinkles forming leak paths identical to that of Mulhauser, one of ordinary skill in the art would expect it to respond in the same manner to temporary increases in internal bowel pressure by also contracting slightly, and thus in even in the configuration wherein the film overlies and covers the stoma the instant film will also tend to be sucked slightly into the stoma as it contracts in response to changes in internal bowel pressure in the same manner as the prior art film.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that the thin flexible seal film of Mulhauser could either be in a form where it protrudes into the stoma or lies flat over the stoma as these are the only possible two locations for the film and in either instance the film will contract into the stoma in response to temporary increases or decreases in internal bowel pressure.

In the alternative, Kay discloses an ostomy device comprising a chamber being pressurizable with fluid, thus providing motivation for such. As best depicted in Figures 13-15, Kay discloses wherein the seal 22 is a thin flexible film that is situated entirely externally to the body and comprising recess defining means 80, 82 (column 7, lines 5-26). Therefore it would

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have been obvious to one having ordinary skill in the art at the time the invention was made to provide the seal of Mulhauser externally to the body as taught by Kay since Kay states, at column 26-29, that the benefit of providing the seal with this design is that it also is sucked toward the user in response to being pressurized and creates an optimum faceplate to body seal to the users body.

With respect to claim 60, Mulhauser discloses an ostomy device for sealing a stoma 14 to control the passage of liquid and solid waste material through the stoma comprising recess defining means B; adhesive means C situated between and in direct contact with said recess defining means B and the skin 18 surrounding the stoma 14 comprising a continuous, uninterrupted adhesive layer 26 completely surrounding and enclosing the stoma 14 on all sides 16, A, E, F for securing said recess defining means B to the body 18 such that said recess defining means B forms a seal A, 16 with the body completely surrounding and enclosing the stoma on all sides A, 16, E, F; and stoma 14 covering means 16, situated within said recess defining means B, and comprising a continuous, uninterrupted member A adapted to prevent the passage of liquid or solid waste material through the stoma when pressed against the stoma (column 6, lines 22-32), said recess defining means B defining, with said stoma covering means 16, a chamber with a sealable fluid entrance port 20, said chamber being situated over said stoma covering means 16 and pressurizable D through said fluid entrance port 20 to press said member A against the stoma (column 6, lines 31-33).

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## Allowable Subject Matter

Claim 49 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the closest prior art of record, Mulhauser, disclose gas filtration means connected to the chamber but does not teach gas filtration means operably connected to a second chamber.

## **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-38 and 40-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 11-17 of copending Application No. 11/430,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '542 application claims means for preventing passage of liquid and solid material through a stoma, adhesive means surrounding a stoma and pressurizable means for pressing the preventing means against a stoma

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## **Response to Arguments**

Applicant's arguments with respect to claims 35-38 and 40-60 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/ Examiner, Art Unit 3761 12/04/10

/Tatyana Zalukaeva/ Supervisory Patent Examiner, Art Unit 3761